

Exhibit 11

Report of Dr. Michael Greger, M.D. FACLM

Dated May 8, 2017

PREPARED FOR:
The Law Office of Jack Fitzgerald, PC &
The Law Office of Paul K. Joseph, PC

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Introduction

Project Description

The Law Office of Jack Fitzgerald, PC and The Law Office of Paul K. Joseph, PC (collectively “Plaintiffs’ Counsel”) have engaged me in connection with the action styled *Preston Jones v. Nutiva, Inc.*, No. 16-cv-711-HSG, pending in the Northern District of California. Specifically, I have been engaged to:

- (a) Identify, analyze, and summarize relevant scientific and medical literature regarding the physiological effects of coconut oil consumption on the human body;
- (b) Analyze and summarize any additional sources Nutiva claims as substantiation for certain statements challenged in this lawsuit, which are made in the labeling of Nutiva’s Extra Virgin Coconut Oil, Virgin Coconut Oil, and Refined Coconut Oil;
- (c) Opine on (i) whether consuming coconut oil is healthy or unhealthy, and (ii) whether it is a healthy replacement for butter; and
- (d) Opine on the veracity of the Nutiva labeling statements challenged in this lawsuit in light of my review of the scientific evidence.

In addition, I anticipate I may be called upon to provide supplemental opinion concerning the matters discussed herein, and to provide rebuttal opinion in response to expert testimony offered by Nutiva.

Summary of Opinions

The relevant scientific literature demonstrates that coconut oil consumption substantially increases cardiovascular and metabolic disease risk by adversely affecting blood lipids, artery function, and insulin sensitivity.

Given the science, it is my opinion, as further detailed herein, that consuming coconut oil is unhealthy, and is not a healthy replacement for butter, as both cause significant harm to health. Accordingly, I believe Nutiva’s labeling is false and misleading inasmuch as it states expressly or suggests that its coconut oil products are healthy or can be healthy replacements for butter.

Background

Qualifications

I graduated from Cornell University School of Agriculture, and Tufts University School of Medicine. I am a physician, licensed as a general practitioner specializing in clinical nutrition. I am a founding member and a Fellow of the American College of Lifestyle Medicine.

I am also a frequent author and speaker. My books include *Bird Flu: A Virus of Our Own Hatching*, *Carbophobia: The Scary Truth Behind America's Low Carb Craze*, and *How Not to Die*, which became an instant New York Times bestseller. My work has been published in peer-reviewed journals including the *American Journal of Preventative Medicine*; *Critical Reviews in Microbiology, Family, and Community Health*; and the *International Journal of Food Safety, Nutrition, and Public Health*.

As an internationally-recognized speaker on nutrition, food safety, and public health issues, I have lectured at the Conference on World Affairs, the National Institutes of Health, and the International Bird Flu Summit, among countless other symposia and institutes, and I have also testified before Congressional subcommittees.

I currently serve as Research Director for a 501(c)(3) nonprofit entity called NutritionFacts.org, which is a science-based, strictly non-commercial website that provides informational videos and articles on the latest evidenced-based nutrition research. Last year alone, I supervised 19 researchers, performed comprehensive medical literature searches on scores of topics and downloaded and categorized more than 18,000 scientific journal articles. The wealth of information in these articles and medical literature is extracted, summarized, and presented in free informational videos and articles on the NutritionFacts.org website, designed to allow lay persons understand and apply the latest evidence-based nutrition research to their daily lives.

I have access to the major online medical databases such as PubMed, Web of Science, and ProQuest, which are considered the customary or standard databases for conducting literary reviews in my profession. I am also in close proximity to the National Library of Medicine, the largest medical library in the world. These online databases and the National Library of Medicine afford me extensive access to the world's academic literature. Since I founded NutritionFacts.org, I have personally searched and analyzed research on more than 2,000 health and nutrition topics, including coconut oil, and thus am well versed in literary reviews.

My curriculum vitae, attached as Exhibit 2, further describes my professional credentials, including identifying all academic publications I have authored in the previous 10 years.

Prior Expert Testimony

The cases in which, during the previous 4 years, I have testified as an expert at trial or by deposition are as follows:

1. *HSUS et al v. FDA*, Consolidated Cases Nos. 14-04932-YGR and 14-04933-YGR (N.D. Cal. 2015);
2. *HSUS et al. v. Hanor Co. of Wisconsin, LLC*, 4:15-cv-00109-FL (E.D.N.C., filed October 21, 2015);
3. *Waterkeeper et. al v. EPA*, D.C. Cir. Case No. 09-1017 (filed March 19, 2015); and
4. *Chase et al. v. Goya Foods, Inc.*, No. 30-2014-00728860-CU-NP-CJC (Cal. Superior Ct., Orange County).

Compensation

I was retained to provide expert services at a rate of \$250 per hour (with travel time billed at half that hourly rate). The money paid for my services was donated to my 501(3)(c) charity. Compensation for my services is not dependent on the opinions I reach or on the outcome of the litigation.

Scope of Project

I understand plaintiffs allege that Nutiva, through a variety of labeling statements, advertises its Extra Virgin, Virgin, and Refined Coconut Oil products as both generally healthy, and as a healthy alternative to butter, and that this advertising is false and misleading because coconut oil is actually unhealthy, and not a healthy substitute for butter.¹

¹ See Dkt. No. 2-1, Compl. ¶¶ 1, 56-63; Dkt. No. 22, Sept. 22, 2016 Order at 2.

In the most general terms, I was asked by Plaintiffs' Counsel to provide expert opinion on whether coconut oil is generally healthy, and a healthy substitute for butter, and as a result, whether Nutiva's labeling claims stating expressly or suggesting that its coconut oil products are healthy, or a healthy substitute for butter, are accurate. This project consisted of four stages.

First, I was asked to conduct a comprehensive survey of the scientific literature to identify any medical literature that studied coconut oil. I was then to review these studies to determine their likely relevance and reliability, so as to identify a universe of all coconut oil literature to be analyzed and relied upon in forming my opinions.

Second, I was asked to consider any further materials, if not already considered, on which Nutiva has indicated it relied to substantiate certain labeling claims that plaintiffs challenge in this lawsuit.

Third, I was asked to render an opinion as to (1) whether coconut oil can generally be considered a healthy or unhealthy oil, and (2) whether coconut oil is a healthy substitute for butter.

Finally, I was asked to render an opinion in light of the scientific evidence, as to the veracity of certain labeling statements challenged in this lawsuit stating expressly or suggesting that the Nutiva coconut oil products are healthy, or a healthy substitute for butter.

Methodology

Identification and Survey of the Scientific Literature Relevant to Coconut Oil

My first task was to perform as exhaustive a review of the literature as reasonably possible, first to identify the relevant scientific and medical literature regarding the physiological effects of coconut oil, then to analyze and summarize it.

I did this by performing, on August 30, 2016, a Boolean search of the National Library of Medicine's Medical Literature Analysis and Retrieval System Online via PubMed without language or date limits using the search string ("Plant Oils"[Mesh] "cocos"[MeSH Terms]) OR "coconut fat" OR "coconut oil"[Supplementary Concept] OR "coconut oil"[All Fields]). This netted 1,784 results (1,728 of which

classified as English, 296 as on humans, 62 as published within the last year, and 44 as reviews).

This was then supplemented with a Web of Science search without language or date limits of their SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, and CCR-EXPANDED databases for “coconut oil” in the following categories: Food Science Technology OR Nutrition Dietetics OR Cardiac Cardiovascular Systems OR Biochemistry Molecular Biology OR Parasitology OR Neurosciences OR Pediatrics OR Pharmacology Pharmacy OR Oncology OR Medicine General Internal OR Ophthalmology OR Integrative Complementary Medicine OR Dentistry OR Surgery Medicine OR Biology OR Gastroenterology Hepatology OR Behavioral Sciences OR Peripheral Vascular Disease OR Allergy OR Toxicology OR Medicine Research Experimental OR Chemistry Physical OR Tropical Medicine OR Mycology OR Reproductive Biology OR Pathology OR Obstetrics Gynecology OR Urology Nephrology OR Dermatology OR Developmental Biology OR Critical Care Medicine OR Chemistry Medicinal OR Clinical Neurology OR Hematology OR Immunology, netting 1,432 results.

The combined searches identified approximately 2,400 unique articles in the peer-reviewed medical literature. From this list I determined that 160 of the articles were relevant to the questions here based on title and abstract scrutiny. I then downloaded, categorized, and read these articles. Iterative citation searching identified 93 additional sources, which I retrieved and analyzed as well.

Subsequently, and just prior to submitting this report, I performed additional searches for recently-published articles on coconut oil, which returned two relevant review articles, and a recent March 2013 intervention trial, which are discussed herein.

Review of Nutiva’s Substantiation

Following my own review of the literature, I was asked to review any additional sources of potential substantiation identified by Nutiva.

I understand that as part of the discovery in this action, Nutiva was required to “Identify any study, testing result, scientific or research paper, or other DOCUMENT or information on which YOU rely, or on which you relied at any time

during the CLASS PERIOD, as a basis for any of the NUTIVA COCONUT OIL CLAIMS.”²

I understand that, in response, Nutiva referred to “documents identified as NUT00156-NUT00180.”³ Plaintiffs’ counsel provided these documents to me, which are identified in the table below.

NUT156-64	Charlotte Cox, et al., “Effects of coconut oil, butter, and safflower oil on lipids and lipoproteins in persons with moderately elevated cholesterol levels,” J. Lipid Research, Vol. 36, pp. 1787-95 (1995)
NUT165-70	Naohisa Nosaka, et al., “Effects of Dietary Medium-Chain Triacylglycerols on Serum Lipoproteins and Biochemical Parameters in Healthy Men,” Biosci. Biotechnol. Biochem., Vol. 66, No. 8, pp. 1713-18 (2002)
NUT171-80	H. Zevenbergen, et al., “Foods with a High Fat Quality Are Essential for Healthy Diets,” Annals of Nutrition & Metabolism, Vol. 54 (suppl 1), pp. 15-24 (2009)

In addition to the above documents, I understand Nutiva has, at times, referred to a book called *The Coconut Oil Miracle*, by Bruce Fife, N.D. For example, in an apparent PowerPoint presentation to its distributor, KeHe, Nutiva states that *The Coconut Oil Miracle* is a “Great read on the benefits of coconut oils with science backed studies.”⁴ On several occasions, Nutiva referred consumers to the book, as well as Mr. Fife’s website.⁵ And I am informed Nutiva’s website previously referred to the book.

Accordingly, I reviewed the sources cited in *The Coconut Oil Miracle* to identify any potential sources that had not been identified as a result of my survey. I then reviewed and analyzed these sources, which include:

² Plaintiff’s Interrogatory No. 4 to Nutiva, dated March 21, 2016.

³ Nutiva’s Response to Interrogatory No. 4, dated May 5, 2016.

⁴ KEHE598

⁵ See, e.g., NUT422, 460, 479, 481, 482, 555, 556, 561, 564, 790, 1040.

1. Baba, N. 1981. Enhanced thermogenesis and diminished deposition of fat in response to overfeeding with a diet containing medium chain triglycerides. *American Journal of Clinical Nutrition* 35.
2. Danesh, J. et al. 1997. Chronic infections and coronary heart disease: Is there a link? *Lancet* 350.
3. Geliebter, A. 1983. Overfeeding with medium-chain triglycerides diet results in diminished deposition of fat. *American Journal of Clinical Nutrition* 37.
4. Hornung, B., et al. 1994. Lauric acid inhibits the maturation of vesicular stomatitis virus. *Journal of General Virology* 75.
5. Mendis, S., and R. Kumarasunderam. 1990. The effect of daily consumption of coconut fat and soya-bean fat on plasma lipids and lipoproteins of young normolipidaemic men. *British Journal of Nutrition* 63.
6. Prior, I.A., et al. 1981. Cholesterol, coconuts, and diet on Polynesian atolls: A natural experiment: The Pukapuka and Tokelau Island studies. *American Journal of Clinical Nutrition* 34(8).
7. Stanhope, J.M., et al. 1981. The Tokelau Island migrant study: Serum lipid concentrations in two environments. *Journal of Chronic Diseases* 34.
8. Seaton, T.B., et al. 1986. Thermic effect of medium-chain and long-chain triglycerides in man. *American Journal of Clinical Nutrition* 44.

Consideration of Whether Coconut Oil is Generally Healthy, and a Healthy Replacement for Butter

After reviewing and analyzing both the literature my survey located, and the sources Nutiva has cited as substantiation for its labeling claims, I considered two questions in light of the totality of the scientific evidence. First, is coconut oil a healthy or unhealthy oil? Second, is coconut oil a healthy substitute for butter? My conclusions in response to these questions are set forth in the Conclusions section below. Those conclusions follow from the detailed analysis of coconut oil's physiological effects, set forth in the Analysis section below.

Consideration of the Challenged Labeling Statements

To opine about the veracity of certain challenged statements made on the labels of Nutiva’s coconut oil products, I reviewed the operative Complaint and exemplars of the labels, and spoke to Plaintiffs’ Counsel regarding the labeling statements being challenged in this lawsuit. Based on those conversations, I understand that plaintiffs intend to seek class certification with respect to the following challenged products and labeling claims, which are summarized as follows.

Extra Virgin Coconut Oil	Virgin Coconut Oil
“100% Less Cholesterol than Butter”	“100% Less Cholesterol than Butter”
“Zero Trans Fats”	“0g trans fat”
“a nutritious substitute in baking”	“A nutritious substitute in baking”
“a ‘better-than-butter’ replacement on bread, vegetables, or popcorn”	“is “better than butter” on bread, vegetables or popcorn”
	“Superfood”

I understand these labeling claims appeared on labels that included other statements giving further context to these claims, such as “non-hydrogenated,” “nature’s ideal all-purpose oil,” “one of the world’s most nourishing foods,” “nourishing people & planet,” “Contains 62% medium chain triglycerides (MCTs) along with lauric and caprylic acids,” and “Nurture Vitality.”

I understand and accept for purposes of rendering my opinion, that even though some labeling statements that plaintiffs challenge may be literally true—for example, that Nutiva coconut oil contains “100% less cholesterol than butter,” since coconut oil contains no cholesterol—plaintiffs nevertheless assert they are misleading because they suggest the Nutiva coconut oil is a healthy replacement for butter and will not detriment cholesterol levels. I have been informed that literally true labeling statements may be considered deceptive if couched in a manner that is likely to mislead.

Analysis

Heart Health & Cardiovascular Disease

According to 200 of the country's leading experts in cardiovascular diseases, representing 29 national medical organizations including the American Heart Association and the American College of Cardiology,⁶ we've known for nearly a half century that "Coconut oil is one of the most potent agents for elevating serum cholesterol level."⁷ Studies showing coconut oil raises cholesterol date back to at least 1955.⁸

Randomized controlled studies show that consuming coconut oil has a pronounced negative physiological impact that increases risk of cardiovascular disease, the leading killer of men and women in the US.

It is well known that total and LDL cholesterol blood levels are two of the most important risk factors in predicting coronary heart disease (CHD), with higher total and LDL cholesterol levels associated with increased risk of CHD. Seven out of seven coconut oil intervention trials resulted in higher LDL levels, demonstrating coconut oil's harmful effects (six out of seven statistically significantly so).

For example, studies show that within just hours of consumption, coconut oil can significantly raise cholesterol levels⁹ and inhibit arterial endothelial function.¹⁰ High

⁶ Wright IS., *Editorial: Cardiovascular diseases-guidelines for prevention and care resources*, Circulation, 1974;49(3):387-9.

⁷ Fowler RL., *Filled milks, coconut oil, and atherosclerosis*, Pediatrics, 1973;51(3):583-4.

⁸ Kinsell L., et al., *Letter to the Editor: In Reply to Comments in Nutrition Reviews*, Am. J. Clin. Nutrition, 1955;3:247-53.

⁹ Myhrstad MC., et al., *Effect of the fat composition of a single high-fat meal on inflammatory markers in healthy young women*, Brit. J. Nutr. 2011;106(12):1826-35.

¹⁰ Nicholls SJ., et al., *Consumption of saturated fat impairs the anti-inflammatory properties of high-density lipoproteins and endothelial function*, J. Am. Coll. Cardiol. 2006;48(4):715-20.

total and LDL-Cholesterol levels, and arterial endothelial function are key risk factors for heart disease and predictors of cardiovascular events such as heart attacks, stroke, and death.¹¹ These studies demonstrate that those who consume coconut oil will suffer adverse physiological effects almost immediately, and these effects are directly related to increased risk of CHD and related events.

Other studies examining the effects of consuming coconut oil in the long term further evidence that coconut oil consumption increases risk of CHD and related events such as heart attacks, stroke, and death. A 62 week intervention study, for instance, that reduced the quantity of coconut fat (CF) in the diet and replaced it with unsaturated fats, showed that reducing coconut oil consumption “results in a lipid profile that is associated with a low cardiovascular risk.”¹² In two phases, researchers reduced the amount of coconut fat in the diet from 17.8% of energy (approximately 2.75 tablespoons of coconut oil)¹³ to 4.7% (approximately 0.75 tablespoons), which resulted in a 11.9% reduction in total cholesterol and a 21.8% reduction in LDL cholesterol. Based on the well-established linear relationship between cholesterol levels and the incidence of CHD, the authors estimated that “the reduction in coronary morbidity and mortality brought about by the current dietary intervention would be of the order of about 6-8 %.”¹⁴

The medical literature demonstrates that even the medium chain triglyceride (MCT) component of coconut oil may raise cholesterol as much as the longer chain saturated fats also contained in coconut oil.¹⁵ Coconut oil significantly raises total and LDL

¹¹ Matsuzawa, J., et al., *Prognostic Value of Flow-Mediated Vasodilation in Brachial Artery and Fingertip Artery for Cardiovascular Events: A Systematic Review and Meta-Analysis*, J. Am. Heart Assoc. 2015;4(11).

¹² Mendis, S., et al., *Coconut fat and serum lipoproteins: effects of partial replacement with unsaturated fats*, 85 Brit. J. Nutr. 2001; 583.

¹³ Based on a 2,000 calorie diet, 17.8% of energy is 356 calories. According to Nutiva’s labels, there are 130 calories in each tablespoon of coconut oil, thus $356(\text{calories})/130(\text{calories/tablespoon}) = 2.74$ tablespoons.

¹⁴ Mendis, *supra* n.12 at 588.

¹⁵ Cater NB., et al., *Comparison of the effects of medium-chain triacylglycerols, palm oil, and high oleic acid sunflower oil on plasma triacylglycerol fatty acids and lipid and lipoprotein concentrations in humans*, Am. J. Clin. Nutr. 1997;65(1):41-5.

“bad” cholesterol compared to olive oil.^{16,17} Compared to safflower oil, randomized crossover trials have found that coconut oil significantly raises total and LDL cholesterol in a way similar to tallow (beef fat).^{18,19,20} The same was found comparing coconut oil to palm, and especially corn oil.²¹ Coconut oil also raises total and LDL cholesterol compared to canola oil.²² Compared to corn oil, coconut oil can also shift the distribution of apolipoprotein E toward VLDL cholesterol fractions, another adverse effect.²³ Replacing some coconut oil in the diet with soybean and sesame oil resulted in a significant improvement in cholesterol levels.²⁴

¹⁶ Ng TK., et al., *Dietary palmitic and oleic acids exert similar effects on serum cholesterol and lipoprotein profiles in normocholesterolemic men and women*, J. Am. Coll. Nutr. 1992;11(4)

¹⁷ Voon PT., et al., *Diets high in palmitic acid (16:0), lauric and myristic acids (12:0 + 14:0), or oleic acid (18:1) do not alter postprandial or fasting plasma homocysteine and inflammatory markers in healthy Malaysian adults*, Am. J. Clin. Nutr. 2011;94(6):1451-7.

¹⁸ Cox C., et al., *Effects of dietary coconut oil, butter and safflower oil on plasma lipids, lipoproteins and lathosterol levels*, Eur. J. Clin. Nutr. 1998;52(9):650-4.

¹⁹ Cox C., et al., *Effects of coconut oil, butter, and safflower oil on lipids and lipoproteins in persons with moderately elevated cholesterol levels*, J. Lipid Res. 1995;36:1787-1795.

²⁰ Reiser R., et al., *Plasma lipid and lipoprotein response of humans to beef fat, coconut oil and safflower oil*, Am. J. Clin. Nutr. 1985;42(2):190-7.

²¹ Ng TK., et al., *Nonhypercholesterolemic effects of a palm-oil diet in Malaysian volunteers*, Am. J. Clin. Nutr. 1991;53(4 Suppl.):1015S-1020S.

²² Mckenney JM., et al., *The effect of supplemental dietary fat on plasma cholesterol levels in lovastatin-treated hypercholesterolemic patients*, Pharmacotherapy 1995;15(5):565-72.

²³ Fisher EA., et al., *Independent effects of dietary saturated fat and cholesterol on plasma lipids, lipoproteins, and apolipoprotein*, E. J. Lipid Res. 1983;24(8):1039-48.

²⁴ Mendis, *supra* n.12.

That coconut oil can also increase HDL levels,^{25,26,27,28,29} at one time considered “good” cholesterol, does not necessarily indicate a protective effect.³⁰ The benefits of raising HDL have been called into question in recent years by Mendelian randomization studies³¹ and failed interventional trials.³² “While the meaning of HDL levels remains uncertain,” the Harvard Heart Letter concluded, “the role of LDL cholesterol in heart disease is solidly established. High levels of LDL cholesterol have been shown to increase the risk of heart attack, and lowering high LDL can decrease this risk.”³³

Indeed, seven out of seven coconut oil intervention trials resulted in higher LDL levels, six out of seven statistically significantly so. Thus, as a 2016 review specifically written to assess coconut oil consumption and cardiovascular risk factors in humans concluded, “consuming cis unsaturated fat [non-hydrogenated plant oils] in place of coconut oil is likely to result in substantial reductions in the risk of CVD [cardiovascular disease].”³⁴ On the other hand, using the best available estimate of a 23% change in risk of major vascular events for each mmol/L change in LDL,³⁵ daily

²⁵ Ng TK., et al., *supra* n.16.

²⁶ Voon PT., et al., *supra* n.17.

²⁷ Cox C., et al., *supra* n.18.

²⁸ Cox C., et al., *supra* n.19.

²⁹ Reiser R., et al., *supra* n.20.

³⁰ Lockyer S., et al., *Coconut oil—a nutty idea?*, Nutr. Bulletin. 2016;41(1):42-54.

³¹ Voight BF., et al., *Plasma HDL cholesterol and risk of myocardial infarction: a mendelian randomisation study*, Lancet. 2012;380(9841):572-80.

³² Hovingh GK., et al. *HDL re-examined*, Curr. Opin. Lipidol. 2015;26(2):127-32.

³³ *High HDL may not protect the heart*, Harvard Heart Letter, September, 2012:6.

³⁴ Eyres L. et al., *Coconut oil consumption and cardiovascular risk factors in humans*, Nutr. Rev. 2016;74(4):267-80.

³⁵ Silverman MG., et al., *Association Between Lowering LDL-C and Cardiovascular Risk Reduction Among Different Therapeutic Interventions: A Systematic Review and Meta-analysis*, JAMA. 2016;316(12):1289-97.

incorporation of under 3 tablespoons of coconut oil in the diet for a period of just six months might be expected to raise the risk of coronary death or heart attack 7%.³⁶

Due to the limitations of establishing cause-and-effect in population studies, the most powerful causal evidence of harm or benefit can be obtained from interventional trials, where food items can be directly put to the test. A new four-week long randomized, controlled, crossover intervention trial comparing the impact of two daily tablespoons of virgin coconut oil with two safflower oil was just published in March 2017.³⁷ In terms of cardiovascular risk, the study found that coconut oil appears even worse than previously understood. Prior comparisons to safflower oil found that approximately 3 tablespoons of coconut oil increased LDL about 8%. This new study, utilizing only 2 tablespoons of coconut oil a day, showed about a 14% increase in LDL cholesterol compared to control within a month,³⁸ signifying an even greater risk of coronary death or heart attack.³⁹ There was an increase in HDL noted, but as the National Lipid Association concluded, when it comes to coconut oil: “The increase in HDL-C[holesterol] is of uncertain clinical relevance, but the increase in LDL-C[holesterol] would be expected to have an adverse effect on ASCVD [atherosclerotic cardiovascular disease] risk.”⁴⁰

The studies cited by Nutiva as substantiation for its claims do not demonstrate that coconut oil is either healthy or a healthy substitute for butter.

³⁶ See Cox C., et al., *supra* n.19. Subjects in the study ate 39g of total fat from coconut oil for a period of 6 months. Because coconut oil has 14g of total fat per tablespoon, this represents approximately 2.8 tablespoons per day. The label of Defendants’ Nature’s Way Extra Virgin Coconut Oil recommends consuming 1-4 tablespoons per day.

³⁷ Harris M., et al., *The Impact of Virgin Coconut Oil and High-Oleic Safflower Oil on Body Composition, Lipids, and Inflammatory Markers in Postmenopausal Women*, J. Med. Food. (2017).

³⁸ *Id.*

³⁹ Silverman MG., et al., *supra* n.35.

⁴⁰ Jacobson TA. et al., *National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 2*, 9 J. Clin. Lipidol. 1 (2015).

First, Nutiva cites one of two published comparisons of coconut oil and butter by Cox, et al., which found that *both* coconut oil and butter raised LDL cholesterol.^{41,42} Compared to safflower oil, butter raised LDL 15-17% whereas coconut oil raised LDL 8%. Using the best available estimate of a 23% change in risk of major vascular events for each mmol/L change in LDL,⁴³ incorporation of coconut oil in the diet as described by Cox, et al. might be expected to raise the risk of coronary death or heart attack 7%, while butter might raise risk 13-14%. Thus, these studies show that while butter has a more pronounced effect on LDL, both are unhealthy and significantly increase risk of heart disease and even death.

The remaining two documents cited by Nutiva are irrelevant because neither studied coconut oil. The first (Zevenbergen, et al.,⁴⁴ identified as NUT171-80) is irrelevant because it specifically excludes coconut oil from its list of higher quality fats due its saturated fat content. The second (Nosaka, et al.,⁴⁵ identified as NUT165-1870) is also irrelevant, since it tested purified medium-chain triglycerides, which lack the cholesterol-raising long-chain saturated fats found in coconut oil. As noted in a recent 2016 review on coconut oil consumption and cardiovascular risk factors:

“Research on manufactured medium-chain triglycerides in the literature cannot be applied to coconut oil because the triglycerides predominant in coconut oil are different in their structure, absorption, and metabolism It is therefore inaccurate to consider coconut oil to contain either predominantly medium-chain fatty acids or

⁴¹ Cox C., et al., *supra* n.18.

⁴² Cox C., et al., *supra* n.19.

⁴³ Silverman MG et al., *Association Between Lowering LDL-C and Cardiovascular Risk Reduction Among Different Therapeutic Interventions: A Systematic Review and Meta-analysis* 316 JAMA 1289 (2016).

⁴⁴ H. Zevenbergen, et al., “Foods with a High Fat Quality Are Essential for Healthy Diets,” *Annals of Nutrition & Metabolism*, Vol. 54 (suppl 1), pp. 15-24 (2009).

⁴⁵ Nosaka N., et al. *Effects of dietary medium-chain triacylglycerols on serum lipoproteins and biochemical parameters in healthy men*, *Biosci Biotechnol Biochem.* 2002;66(8):1713-8.

predominantly medium-chain triglycerides. Thus, the evidence on medium-chain triglycerides cannot be extrapolated to coconut oil.”⁴⁶

In addition, Lauric Acid, which comprises about half fat in coconut oil and Nutiva classifies as a medium chain triglyceride, “behaves more as a long-chain fatty acid [terms of digestion and metabolism] because the majority of it (70%–75%) is absorbed with chylomicrons.” “It is therefore inaccurate to consider coconut oil to contain either predominantly medium-chain fatty acids or predominantly medium-chain triglycerides.”⁴⁷

“In summary,” the 2016 review concluded, “this review found no evidence that coconut oil should be viewed differently from other sources of dietary saturated fat with regard to dietary recommendations.”⁴⁸ When coconut oil is put to the test in interventional trials, it raises LDL cholesterol, a leading risk factor for the #1 killer of men and women. This is underscored by Nutiva’s own cited document (Zevenbergen, et al.), which specifically excludes coconut oil from its list of higher quality fats due its saturated fat content. As Dr. Walter Willet, chair of nutrition at Harvard, has said: “Feeding studies in humans...show that coconut oil substantially elevates LDL (bad) cholesterol.” While coconut oil is healthier than trans fats, he said, “coconut and coconut oil can’t be considered heart-healthy foods.”⁴⁹

In addition, a November 2016 review entitled “Progressing Insights into the Role of Dietary Fats in the Prevention of Cardiovascular Disease” concluded:

“Popular belief holds that coconut oil is healthy, a notion not supported by scientific data. Coconut oil is an edible oil with a very high total SAFA content (80%). A common misconception is that the SAFA in coconut oil are mainly medium chain fatty acids, which are metabolized differently from long-chain SAFA. Actually, coconut oil is mainly C12:0 lauric acid and C14:0 myristic acid, which have potent LDL-C-

⁴⁶ *Id.*

⁴⁷ Eyres L., et al., *supra* n.34 at 268-69.

⁴⁸ *Id.*

⁴⁹ Willett WC., *Ask the doctor. I have heard that coconut is bad for the heart and that it is good for the heart. Which is right?*, Harv Heart Lett. 2006;17(1):8.

raising effects. Coconut oil should therefore not be advised for people who should or want to reduce their risk of CHD.”⁵⁰

Finally, the latest review, as of this writing, was published March 2017 in the *Journal of the American College of Cardiology* by the American College of Cardiology’s Prevention of Cardiovascular Disease Council. Their views on coconut oil was summed up in one word: “Avoid.”⁵¹

Inflammation

Coconut oil appears to have a pro-inflammatory effect in humans, raising plasma leukotriene B₄ levels compared to olive oil.⁵² Within 6 hours after a meal containing coconut oil, the anti-inflammatory properties of HDL are impaired, and within 3 hours flow-mediated dilation is also impaired.⁵³ Flow-mediated dilation is a measure of artery function and, as such, is a key predictor of cardiovascular events such as heart attacks, stroke, and death.⁵⁴ Nicholls et al. found that human arterial function can be significantly impaired within hours of consuming coconut oil.⁵⁵

In sum, the evidence demonstrates coconut oil consumption has a pro-inflammatory effect, further increasing risk of CHD and related events.

⁵⁰ Zock PL., et al., *Progressing Insights into the Role of Dietary Fats in the Prevention of Cardiovascular Disease*, Curr. Cardiol. Rep. 2016;18(11):111.

⁵¹ Freeman AM., et al., *Trending Cardiovascular Nutrition Controversies*, J. Am. Coll. Cardiol., 2017;69(9):1172-1187.

⁵² Voon PT., et al., *Virgin olive oil, palm olein and coconut oil diets do not raise cell adhesion molecules and thrombogenicity indices in healthy Malaysian adults*, Eur. J. Clin. Nutr. 2015;69(6):712-6.

⁵³ Nicholls SJ., et al., *supra* n.10.

⁵⁴ Matsuzawa, J., et al., *supra* n.11.

⁵⁵ Nicholls SJ., et al., *supra* n.10.

Body Fat

There was no difference in appetite measures or food intake of subjects who consumed coconut oil when compared to subjects to consumed dairy or beef fat.⁵⁶ There are only two placebo-controlled study on coconut oil and anthropometric measures. The first found no significant difference in waist circumference between the group provided with coconut oil for cooking compared to the group provided with soybean oil. But insulin resistance significantly increased in the coconut oil group despite a low-calorie diet and the encouragement of 50 minutes of exercise a day.⁵⁷ Insulin resistance is a characteristic of obesity, and associated with an increased incidence in type 2 diabetes, coronary heart disease, polycystic ovarian syndrome, and hypertension.⁵⁸

In the second placebo-controlled study, just published in March of 2017, found no significant effect of coconut oil over the control in terms of anthropometric data, such as weight loss and abdominal circumference. This is including additional measurements such as fat mass, lean body mass, hip circumference, total percent body fat, total percent android fat, and total percent gynoid fat.⁵⁹

Brain Health & Alzheimer's Disease

I understand that some proponents of coconut oil claim it improves brain health or can be used to treat Alzheimer's disease. But as the Alzheimer's Association has concluded, while "A few people have reported that coconut oil helped the person with Alzheimer's, . . . there's never been any clinical testing of coconut oil for

⁵⁶ Poppitt SD., et al., *Fatty acid chain length, postprandial satiety and food intake in lean men*, *Physiol. Behav.* 2010;101(1):161-7.

⁵⁷ Assunção ML., et al., *Effects of dietary coconut oil on the biochemical and anthropometric profiles of women presenting abdominal obesity*, *Lipids*. 2009;44(7):593-601.

⁵⁸ Lebovitz HE., *Insulin resistance: definition and consequences*, *Exp. Clin. Endocrinol. Diabetes*, 2001;109 Suppl. 2:S135-48.

⁵⁹ Harris M., et al. *supra* n.37.

Alzheimer's, and there's no scientific evidence that it helps."⁶⁰ This is further echoed in the peer-reviewed literature.⁶¹

While the manufacturer of an MCT product ("AC-1202," marketed as Axona) performed a study that found cognitive improvements for a small subset of subjects, the cognitive effects were not significant in the overall sample of patients.⁶² Further, unlike the coconut oils at issue here, Axona is over 95% caprylic acid,⁶³ whereas coconut oil is only about 7% caprylic.⁶⁴ Further, coconut oil also has longer chain saturated fats that have been associated with increased risk and progression of Alzheimer's disease.⁶⁵

Thus the medical literature fails to demonstrate that consuming coconut oil benefits brain health.

Conclusions

The scientific community has known for more than a half century that coconut oil consumption adversely impacts cardiovascular risk by raising blood cholesterol levels. The majority of studies subsequently published in the peer reviewed medical literature have since validated this initial assessment. Coconut oil has also been shown to have a pro-inflammatory effect in humans, to impair artery function within hours of consumption, and to worsen insulin resistance, a pathological condition considered a precursor to type 2 diabetes. At the same time, claims regarding

⁶⁰ Alzheimer's Association, "Alternative Treatments," at http://www.alz.org/alzheimers_disease_alternative_treatments.asp.

⁶¹ Swaminathan A., et al., *Nutrition and prevention of Alzheimer's dementia*, Front Aging Neurosci. 2014;6:282.

⁶² Henderson ST., et al., *Study of the ketogenic agent AC-1202 in mild to moderate Alzheimer's disease: a randomized, double-blind, placebo-controlled, multicenter trial*, Nutr. Metab. (Lond). 2009;6:31.

⁶³ *Id.*

⁶⁴ Alzheimer's Association, "Medical Foods," 2015:1 available at http://www.alz.org/documents_custom/statements/Medical_Foods.pdf.

⁶⁵ Barnard ND., et al., *Saturated and trans fats and dementia: a systematic review*, Neurobiol. Aging. 2014;35 Suppl. 2:S65-73.

purported benefits of consuming coconut oil on abdominal fat or brain health remain unsupported by the peer-reviewed medical literature.

Therefore, based on the best available scientific evidence, it is my opinion that:

- (1) consuming coconut oil is not healthy;
- (2) coconut oil consumption is not a healthy substitute for butter; and
- (3) Nutiva's Coconut Oil labeling claims stating or suggesting the products are healthy or a healthy substitute to butter, are false or misleading.

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